

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0000055340	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/EP2004/008623	International filing date (day/month/year) 31.07.2004	Priority date (day/month/year) 18.08.2003
International Patent Classification (IPC) or national classification and IPC C12P23/00, C12N15/82, A23K1/00, C12N15/63		
Applicant SUNGENE GMBH & CO. KGAA		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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International application No.

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Box No. I

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-126 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages** _____ received by this Authority on _____
- ☒ the claims:
- nos. 1-71 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.** _____ received by this Authority on _____
- nos.** _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets** _____ received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-71	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-71	NO
Industrial applicability (IA)	Claims	1-71	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
Reference is made to the following documents:			
D1: WO 02/079395 A (CARGILL INC.) 10 October 2002 (2002-10-10)			
D2: EP-A-0 725 137 (KIRIN BREWERY) 7 August 1996 (1996-08-07)			
D3: DE 102 38 980 A (SUNGENE GMBH & CO KGAA) 4 March 2004 (2004-03-04)			
D4: DE 102 53 112 A (SUNGENE GMBH & CO KGAA) 3 June 2004 (2004-06-03)			
D5: DE 102 58 971 A (SUNGENE GMBH & CO KGAA) 1 July 2004 (2004-07-01)			
D7: Ronen G. et al.: 'An alternative pathway to beta- carotene formation in plant chromoplasts discovered by map-based cloning of Beta and old- gold color mutations in tomato', Proceedings of the National Academy of Sciences, USA; September 26, 2000 (26-09-2000).			
1. Claimed priorities			
The present application claims priorities of seven international applications. These international			

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Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

applications in turn likewise claim different (national) priorities. Article 4 of the Paris Convention for the Protection of Industrial Property and PCT Article 8 state that a priority right for a particular subject matter can be claimed for a single period of 12 months. In the case of the present application this means that the subject matter of older, national priorities no longer enjoys the (further) priority of the more recent seven international applications claimed for the present application; in other words, the seven international priorities claimed for the present application are taken into consideration only insofar as they do not relate to the subject matter of the different national priorities. It follows further that the overlapping content of the different national priorities, insofar as it was published prior to the international filing date 31 July 2004, is considered the prior art with regard to the present application.

2. Novelty and inventive step (PCT Article 33(2) and (3))

- 2.1** The present application concerns transgenic organisms which overexpress ketolase and a defined beta-cyclase, possibly in combination with a hydroxylase and further enzymes of the carotenoid pathway, in order to produce ketocarotenoids. Methods of production and the use of the transgenic organisms as food or animal feed, and

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Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

the production thereof, are likewise claimed.

- 2.2** Document D1 discloses methods for the production of the ketocarotenoids astaxanthin and canthaxanthin in plants and microorganisms, by the overexpression of, *inter alia*, beta-cyclase and ketolase (here: "beta-carotene C4 oxygenase"), possibly in combination with hydroxylase (page 22, line 22, to page 23, line 10). Moreover, the use of these plants or microorganisms as food or animal feed and the production thereof are likewise mentioned (page 1, lines 20-27; page 25, line 6, to page 26, line 30).
- 2.3** Document D2 relates to a method for the production of ketocarotenoids, wherein a ketolase activity (here: "bkt"), together with further enzymes of the carotenoid pathway, such as, for example, beta-cyclase ("crtY") and possibly hydroxylase ("crtZ") is overexpressed in microorganisms (page 6, line 34, to page 7, line 39).
- 2.4** Documents D3 to D6 disclose how particular ketocarotenoids can be produced in plants, or organisms, by the expression of plant ketolases in combination with plant beta-cyclases and possibly hydroxylases. The use of the transgenic organisms as food or animal feed and the production thereof are likewise claimed (citations: see the international search report).

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
2.5	<p>The subject matter of claims 1-71 is novel with respect to the cited prior art and therefore satisfies the requirements of PCT Article 33(2).</p>
2.6	<p>Unlike documents D1 to D6, the present application claims the expression of a defined beta-cyclase (SEQ ID NO:1; SEQ ID NO:2) whose sequence is already known from document D7 but whose specific use in a method for the production of ketocarotenoids, as mentioned in documents D1 to D6, was not disclosed. Consequently, the subject matter of the present claims 1-71 is novel, but cannot be considered inventive since it is known from each one of documents D1 to D6 that <u>in general</u> beta-cyclase activity in combination with ketolase activity (and possibly hydroxylase activity) is used for the production of ketocarotenoids. The use of the specific beta-cyclase defined in SEQ ID NO:1 and SEQ ID NO:2 for the production of ketocarotenoids therefore constitutes a <u>selection</u> of the group of beta-cyclases generally known from documents D1 to D6 for their use in the production of ketocarotenoids. However, a selection of this kind can be considered inventive only if the specific beta-cyclase has unexpected effects or properties with respect to the remaining beta-cyclases. Effects or properties of this kind are not specified in the application and therefore the subject matter of claims 1-71 does not involve an inventive step within the meaning of PCT Article 33(3).</p>

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Box No. VI

Certain documents cited

1. Certain published documents (Rule 70.10)

Application No.
Patent No.Publication date
(day/month/year)Filing date
(day/month/year)Priority date (valid claim)
(day/month/year)

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)Date of written disclosure
referring to non-written disclosure
(day/month/year)

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
- a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☒ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

The sequence listing in the description, pages 1-212, as originally filed.

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."